Second Regular Session 114th General Assembly (2006)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2005 Regular Session of the General Assembly.

SENATE ENROLLED ACT No. 202

AN ACT to amend the Indiana Code concerning professions and occupations.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-42-19-23 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 23. (a) As used in this section, "mechanical device" means a machine for storage and dispensing of drugs. The term does not include devices or instruments used by practitioners in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.

(b) A person may not maintain, operate, or use any type of mechanical device in which any legend drug or narcotic drug is stored or held for the purpose of dispensing the drug from the mechanical device. However, the mechanical device may be used for the storage and dispensing of legend drugs if:

(1) the mechanical device is ~~located on the premises of a business or establishment holding a valid~~ **used in a:**

(A) pharmacy **that holds a** permit issued by the Indiana board of pharmacy; ~~and~~

(B) remote location under the jurisdiction of the board of pharmacy; or

(C) health care facility that is licensed under IC 16-28 or IC 16-21-2; and

(2) the mechanical device is operated under the direct supervision and control of a:

(A) registered pharmacist; **or**

(B) practitioner;

who is directly responsible for dispensing the drug from the mechanical device.

(c) Inspectors of the Indiana board of pharmacy may inspect the premises of any person suspected of violating this section.

SECTION 2. IC 25-26-13-2, AS AMENDED BY P.L.204-2005, SECTION 14, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 2. As used in this chapter:

"Board" means the Indiana board of pharmacy.

"Controlled drugs" are those drugs on schedules I through V of the Federal Controlled Substances Act or on schedules I through V of IC 35-48-2.

"Counseling" means effective communication between a pharmacist and a patient concerning the contents, drug to drug interactions, route, dosage, form, directions for use, precautions, and effective use of a drug or device to improve the therapeutic outcome of the patient through the effective use of the drug or device.

"Dispensing" means issuing one (1) or more doses of a drug in a suitable container with appropriate labeling for subsequent administration to or use by a patient.

"Drug" means:

(1) articles or substances recognized in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them;

(2) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(3) articles other than food intended to affect the structure or any function of the body of man or animals; or

(4) articles intended for use as a component of any article specified in subdivisions (1) through (3) and devices.

"Drug order" means a written order in a hospital or other health care institution for an ultimate user for any drug or device, issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, which is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution. The order shall contain the name and bed number of the patient; the name and strength or size of the drug or device; unless specified by individual institution policy or guideline, the amount to be dispensed either in quantity or days; adequate directions for the proper use of the drug or

device when it is administered to the patient; and the name of the prescriber.

"Drug regimen review" means the retrospective, concurrent, and prospective review by a pharmacist of a patient's drug related history that includes the following areas:

(1) Evaluation of prescriptions or drug orders and patient records for drug allergies, rational therapy contradictions, appropriate dose and route of administration, appropriate directions for use, or duplicative therapies.

(2) Evaluation of prescriptions or drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions.

(3) Evaluation of prescriptions or drug orders and patient records for adverse drug reactions.

(4) Evaluation of prescriptions or drug orders and patient records for proper utilization and optimal therapeutic outcomes.

"Drug utilization review" means a program designed to measure and assess on a retrospective and prospective basis the proper use of drugs.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component part or accessory, which is:

(1) recognized in the official United States Pharmacopoeia, official National Formulary, or any supplement to them;

(2) intended for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(3) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

"Electronic data intermediary" means an entity that provides the infrastructure that connects a computer system or another electronic device used by a prescribing practitioner with a computer system or another electronic device used by a pharmacy to facilitate the secure transmission of:

(1) an electronic prescription order;

(2) a refill authorization request;

(3) a communication; and

(4) other patient care information;

between a practitioner and a pharmacy.

"Electronic signature" means an electronic sound, symbol, or process:

(1) attached to or logically associated with a record; and

(2) executed or adopted by a person;

with the intent to sign the record.

"Electronically transmitted" or "electronic transmission" means the transmission of a prescription in electronic form. The term does not include the transmission of a prescription by facsimile.

"Investigational or new drug" means any drug which is limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

"Legend drug" has the meaning set forth in IC 16-18-2-199.

"License" and "permit" are interchangeable and mean a written certificate from the Indiana board of pharmacy for the practice of pharmacy or the operation of a pharmacy.

"Nonprescription drug" means a drug that may be sold without a prescription and that is labeled for use by a patient in accordance with state and federal laws.

"Person" means any individual, partnership, copartnership, firm, company, corporation, association, joint stock company, trust, estate, or municipality, or a legal representative or agent, unless this chapter expressly provides otherwise.

"Practitioner" has the meaning set forth in IC 16-42-19-5.

"Pharmacist" means a person licensed under this chapter.

~~"Pharmacist extern" means a pharmacy student enrolled full time in an approved school of pharmacy and who is working in a school sponsored, board approved program related to the practice of pharmacy.~~

"Pharmacist intern" means a person who is: ~~working to secure additional hours of practice and experience prior to making application for a license to practice as a pharmacist.~~

(1) permitted by the board to engage in the practice of pharmacy while under the personal supervision of a pharmacist and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(2) a graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate and who is permitted by the board to obtain practical experience as a requirement for licensure as a pharmacist;

(3) a qualified applicant awaiting examination for licensure;

or

(4) an individual participating in a residency or fellowship program.

"Pharmacy" means any facility, department, or other place where prescriptions are filled or compounded and are sold, dispensed, offered, or displayed for sale and which has as its principal purpose the dispensing of drug and health supplies intended for the general health, welfare, and safety of the public, without placing any other activity on a more important level than the practice of pharmacy.

"The practice of pharmacy" or "the practice of the profession of pharmacy" means a patient oriented health care profession in which pharmacists interact with and counsel patients and with other health care professionals concerning drugs and devices used to enhance patients' wellness, prevent illness, and optimize the outcome of a drug or device, by accepting responsibility for performing or supervising a pharmacist intern ~~a pharmacist extern,~~ or an unlicensed person under section 18(a)(4) of this chapter to do the following acts, services, and operations:

(1) The offering of or performing of those acts, service operations, or transactions incidental to the interpretation, evaluation, and implementation of prescriptions or drug orders.

(2) The compounding, labeling, administering, dispensing, or selling of drugs and devices, including radioactive substances, whether dispensed under a practitioner's prescription or drug order or sold or given directly to the ultimate consumer.

(3) The proper and safe storage and distribution of drugs and devices.

(4) The maintenance of proper records of the receipt, storage, sale, and dispensing of drugs and devices.

(5) Counseling, advising, and educating patients, patients' caregivers, and health care providers and professionals, as necessary, as to the contents, therapeutic values, uses, significant problems, risks, and appropriate manner of use of drugs and devices.

(6) Assessing, recording, and reporting events related to the use of drugs or devices.

(7) Provision of the professional acts, professional decisions, and professional services necessary to maintain all areas of a patient's pharmacy related care as specifically authorized to a pharmacist under this article.

"Prescription" means a written order or an order transmitted by other means of communication from a practitioner to or for an ultimate user

for any drug or device containing:

(1) the name and address of the patient;

(2) the date of issue;

(3) the name and strength or size (if applicable) of the drug or device;

(4) the amount to be dispensed (unless indicated by directions and duration of therapy);

(5) adequate directions for the proper use of the drug or device by the patient;

(6) the name of the practitioner; and

(7) if the prescription:

(A) is in written form, the signature of the practitioner; or

(B) is in electronic form, the electronic signature of the practitioner.

"Qualifying pharmacist" means the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operations of the pharmacy under the permit.

"Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records, or other written indicia, documents, or objects which are used in any way in connection with the purchase, sale, or handling of any drug or device.

"Sale" means every sale and includes:

(1) manufacturing, processing, transporting, handling, packaging, or any other production, preparation, or repackaging;

(2) exposure, offer, or any other proffer;

(3) holding, storing, or any other possession;

(4) dispensing, giving, delivering, or any other supplying; and

(5) applying, administering, or any other using.

SECTION 3. IC 25-26-13-9 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 9. (a) The board shall establish standards for pharmacist intern ~~and pharmacist extern~~ programs. Such standards shall include, but not be limited to, the number of hours students must spend in a program, the number of hours a student must spend in a pharmacy each week, and the types of duties the student may perform.

(b) The board shall, by regulation, establish standards and requirements for continuing education and shall endorse those continuing education programs which meet the standards and requirements.

SECTION 4. IC 25-26-13-10 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 10. (a) An

applicant for registration as a pharmacist intern ~~or pharmacist extern~~ must furnish proof satisfactory to the board that the applicant: ~~is a high school graduate or its equivalent, has obtained a general educational development (GED) diploma, or is enrolled in a pre-pharmacy or pharmacy curriculum at an accredited school of pharmacy. The board may require the applicant to successfully complete an examination prior to registering the applicant as a pharmacist intern or pharmacist extern.~~

(1) is actively enrolled in a school of pharmacy accredited by the American Council of Pharmaceutical Education;

(2) has obtained the Foreign Pharmacy Graduate Examination Committee Certificate; or

(3) is a qualified applicant awaiting the examination for licensure as a pharmacist.

(b) A registration ~~issued~~ under ~~subsection (a) of~~ this section is valid for one (1) year and may be renewed by the board for an additional year until the expiration date established by the ~~health professions bureau~~ **Indiana professional licensing agency** under IC 25-1-5-4.

(c) An application for registration or renewal must be accompanied by the appropriate fee **and one (1) of the following:**

(1) Proof of having obtained the Foreign Pharmacy Graduate Examination Committee Certificate.

(2) Proof of active enrollment in a school of pharmacy accredited by the American Council of Pharmaceutical Education.

SECTION 5. IC 25-26-13-10.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 10.5. (a) A pharmacy intern may engage in the practice of pharmacy if the activities are under the direct supervision of a pharmacist. The pharmacist in charge is responsible for the activities relating to the practice of pharmacy performed by the pharmacy intern.**

(b) A pharmacist shall review in person the prescription drug order and the dispensed product prepared by a pharmacy intern before the product is dispensed to the patient or the patient's agent.

SECTION 6. IC 25-26-13-11 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 11. (a) To be eligible for licensure as a pharmacist, an individual must file such evidence as is required by the board that:

(1) the individual is at least eighteen (18) years of age;

(2) the individual does not have a conviction for a crime that has a direct bearing on the individual's ability to practice competently;

(3) the individual:

(A) has graduated with a professional degree from a school of pharmacy accredited by the American Council of Pharmaceutical Education or the Canadian Council on Pharmacy Accreditation and approved by the board; or

(B) has:

(i) graduated with a professional degree from a school of pharmacy located outside the United States and Canada; and

(ii) met the requirements under subsection (c); and

(4) the individual has satisfactorily completed ~~either~~ a pharmacist intern ~~or pharmacist extern~~ program approved by the board.

(b) An applicant who has graduated with a professional degree from a school of pharmacy accredited by the Canadian Council on Pharmacy Accreditation and approved by the board must ~~pass~~ **obtain** the Foreign Pharmacy Graduate ~~Equivalency~~ Examination ~~(FPGEE)~~ **Committee Certificate** administered by the National Association of Boards of Pharmacy before taking the examination required under subsection (d).

(c) An applicant who has graduated with a professional degree from a school of pharmacy located outside the United States and Canada must do the following:

(1) Provide the board with verification of the applicant's academic record and graduation.

(2) ~~Pass~~ **Obtain** the Foreign Pharmacy Graduate ~~Equivalency~~ Examination ~~(FPGEE)~~ **Committee Certificate** administered by the National Association of Boards of Pharmacy.

~~(3) Pass an examination approved by the board to establish proficiency in English.~~

(d) After filing an application on a form provided by the board, submitting the information required in subsection (a), and successfully completing the examination administered by the board, the applicant may be licensed as a pharmacist.

SECTION 7. IC 25-26-13-12 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 12. (a) An individual who is licensed as a pharmacist in another state where the requirements for licensure were not less than those required in this state at the time of original licensure may be issued a license in this state if:

(1) the individual has registered with and been approved by the National Association of Boards of Pharmacy;

(2) the individual has graduated with a professional degree in pharmacy from a school of pharmacy accredited by the American Council of Pharmaceutical Education or the Canadian Council on

Pharmacy Accreditation and approved by the board; **and**

(3) the individual has successfully completed an examination administered by the board concerning the federal statutes and regulations and the Indiana statutes and rules governing the practice of pharmacy. ~~and~~

~~(4) in the case of an individual who has not been actively engaged in the practice of pharmacy for the twelve (12) months immediately preceding the individual's application, the individual has successfully completed a practical examination administered by the board.~~

(b) An individual who has a professional pharmacy degree from a school of pharmacy located outside the United States and Canada and who is licensed in another state where the requirements for licensure are substantially the same as those in this state may be issued a license under this chapter if:

(1) the individual has registered with and been approved by the National Association of Boards of Pharmacy;

(2) the individual has provided the board with proof of the applicant's:

(A) academic record and graduation with a professional degree from a school of pharmacy; **and**

(B) ~~successful~~ completion of the **requirements for obtaining a** Foreign Pharmacy Graduate ~~Equivalency~~ Examination ~~(FPGEE) approved~~ **Committee Certificate administered** by the National Association of Boards of Pharmacy; and

~~(C) successful completion of an English proficiency examination approved by the board;~~

(3) the individual has successfully completed an examination administered by the board concerning the federal statutes and regulations and the Indiana statutes and rules governing the practice of pharmacy. ~~and~~

~~(4) in the event that the individual has not been actively engaged in the practice of pharmacy in the twelve (12) months preceding the application, the individual has successfully completed a practical examination administered by the board.~~

SECTION 8. IC 25-26-13-14 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 14. (a) A pharmacist's license expires July 1 of each even-numbered year, unless renewed before that date.

(b) If an application for renewal is not filed and the required fee paid before July 1 of each even-numbered year, the license expires and becomes invalid, and may be reinstated only by meeting the

requirements under IC 25-1-8-6.

(c) Subject to IC 25-1-4-3, a statement attesting that the pharmacist has met the continuing education requirements shall be submitted with the application for license renewal.

(d) If a pharmacist surrenders the pharmacist's license to practice pharmacy in Indiana, the board may subsequently consider reinstatement of the pharmacist's license upon written request of the pharmacist. The board may impose any conditions it considers appropriate to the surrender or to the reinstatement of a surrendered license. The practitioner may not voluntarily surrender the practitioner's license to the board without the written consent of the board if any disciplinary proceedings are pending against the practitioner under this chapter or IC 25-1-9.

(e) If a person fails to renew a license that expires under subsection (a) within three (3) years after the date the license expires, the board may reinstate the license only if the person:

(1) meets the requirements under IC 25-1-8-6; and

(2) passes an examination concerning state and federal laws that the board considers relevant to the practice of pharmacy.

(f) The board may require a person who applies for a license under subsection (e) to appear before the board and explain the reason the person failed to renew the person's license.

(g) If a person fails to renew a license that expires under subsection (a) within seven (7) years after the date the license expires, the person must apply for a new license.

SECTION 9. IC 25-26-13-17 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 17. (a) The board shall establish classes of pharmacy permits as follows:

Type I. A retail permit for a pharmacy that provides pharmaceutical care to the general public by the dispensing of a drug or device.

Type II. An institutional permit for hospitals, clinics, health care facilities, sanitariums, nursing homes, or dispensaries that offer pharmaceutical care by dispensing a drug product to an inpatient under a drug order or to an outpatient of the institution under a prescription.

Type III. A permit for a pharmacy that is not:

(A) open to the general public; or

(B) located in an institution listed under a Type II permit;

and provides pharmaceutical care to a patient who is located in an institution or in the patient's home.

Type IV. A permit for a pharmacy not open to the general public

that provides pharmaceutical care by dispensing drugs and devices to patients exclusively through the United States Postal Services or other parcel delivery service.

Type V. A permit for a pharmacy that engages exclusively in the preparation and dispensing of diagnostic or therapeutic radioactive drugs.

Type VI. A permit for a pharmacy open to the general public that provides pharmaceutical care by engaging in an activity under a Type I or Type III permit. A pharmacy that obtains a Type VI permit may provide services to:

(A) a home health care patient;

(B) a long term care facility; or

(C) a member of the general public.

(b) Hospitals holding a Type II permit may offer drugs or devices to an employee, student, or medical staff member or their dependents for their own use.

(c) Nothing in this section prohibits a pharmacy holding a permit other than a Type IV permit from delivering drugs or devices through mail, parcel delivery, or hand delivery.

(d) Hospitals holding a Type II permit may operate remote locations within a reasonable distance of the licensed area, as determined by the board, after:

(1) filing an application on a form prepared by the board;

(2) having each location inspected by the board; and

(3) obtaining approval from the board.

~~(d)~~ **(e)** Any applicable rule governing the practice of pharmacy in Indiana shall apply to all permits under this section.

SECTION 10. IC 25-26-13-20 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 20. (a) A person desiring to open, establish, operate, or maintain a pharmacy shall apply to the board for a pharmacy permit on a form provided by the board. The applicant shall set forth:

(1) the name and occupation of the persons desiring the permit;

(2) the location, including street address and city, of the pharmacy;

(3) the name of the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operation of the pharmacy under the permit; and

(4) such other information as the board may require.

(b) If the applicant desires to open, establish, operate, or maintain more than one (1) pharmacy, he must file a separate application for each. Each pharmacy must be qualified by a different pharmacist.

(c) The board shall permit a pharmacist to serve as a qualifying pharmacist for more than one (1) pharmacy holding a Type II pharmacy permit upon the holder of the Type II permit showing circumstances establishing that:

(1) the permit holder has made a reasonable effort, without success, to obtain a qualifying pharmacist who is not serving as a qualifying pharmacist at another Type II pharmacy; and

(2) the single pharmacist could effectively fulfill all duties and responsibilities of the qualifying pharmacist at both locations.

(d) The board shall grant or deny an application for a permit not later than one hundred twenty (120) days after the application and any additional information required by the board are submitted.

(e) The board may not issue a pharmacy permit to a person who desires to operate the pharmacy out of a residence.

SECTION 11. IC 25-26-13-32 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 32. If a state of emergency is declared by:**

(1) the governor under IC 10-14-3-12; or

(2) the President of the United States;

the board may, for the duration of the state of emergency, suspend the provisions of a statute or rule under this article that would prevent, hinder, or delay the appropriate delivery of pharmaceutical care.

SECTION 12. IC 25-26-14-1, AS AMENDED BY P.L.212-2005, SECTION 23, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 1. (a) This chapter applies to any individual, partnership, limited liability company, corporation, or business firm:

(1) located in or outside Indiana; and

(2) engaging in the wholesale distribution of legend drugs in Indiana.

(b) Except as required by federal law or regulation, the requirements of this chapter do not apply to a manufacturer that is approved by the federal Food and Drug Administration. However, the board may adopt rules concerning manufacturers that the board considers appropriate and necessary.

(c) The requirements of this chapter do not apply to a medical gas manufacturer or distributor that only manufactures or distributes medical gases.

SECTION 13. IC 25-26-14-3.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 3.7. As used in this chapter,**

"chain drug warehouse" means a permanent physical location for drugs or devices, or both, that:

(1) is licensed as a wholesale distributor;

(2) acts as a central warehouse; and

(3) primarily performs intracompany sales and transfers of legend drugs or devices to members of the same affiliated group that is under common ownership and control.

SECTION 14. IC 25-26-14-8.7, AS ADDED BY P.L.212-2005, SECTION 40, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 8.7. As used in this chapter, "pedigree" means a statement or record in a written or an electronic form that is approved by the board, that:

(1) records each **wholesale** distribution of a legend drug from the sale by the manufacturer ~~from the last authorized distributor of record through acquisition and sale by each wholesale drug distributor,~~ **that leaves the normal distribution chain of custody** and that includes information designated by the board through rules for each transaction; **or**

(2) complies with a legend drug pedigree law or regulation in another state or United States territory that meets the pedigree requirements under this chapter.

SECTION 15. IC 25-26-14-12 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 12. As used in this chapter, "wholesale drug distributor" means a person engaged in wholesale distribution of legend drugs, including:

(1) manufacturers;

(2) repackers;

(3) own-label distributors;

(4) private-label distributors;

(5) jobbers;

(6) brokers;

(7) warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;

(8) independent wholesale drug traders; ~~and~~

(9) retail and hospital pharmacies that conduct wholesale distributions; **and**

(10) reverse distributors.

The term does not include a common carrier or person hired solely to transport prescription drugs.

SECTION 16. IC 25-26-14-14.5, AS ADDED BY P.L.212-2005, SECTION 47, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE

UPON PASSAGE]: Sec. 14.5. After June 30, 2006, a wholesale drug distributor may not accept or deliver a legend drug without a current, accompanying pedigree **as required under section 17 of this chapter.**

SECTION 17. IC 25-26-14-15, AS AMENDED BY P.L.212-2005, SECTION 48, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 15. (a) The board shall require the following minimum information from each wholesale drug distributor as part of the license described in section 14 of this chapter and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee.

(2) All trade or business names used by the licensee.

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of legend drugs.

(4) The type of ownership of operation.

(5) The name of each owner and operator of the licensee, including:

(A) if an individual, the name, address, Social Security number, and date of birth of the individual;

(B) if a partnership, the name, address, Social Security number, and date of birth of each partner, and the name of the partnership and federal employer identification number;

(C) if a corporation:

(i) the name, address, Social Security number, date of birth, and title of each corporate officer and director;

(ii) the corporate names, the name of the state of incorporation, the federal employer identification number, and the name of the parent company, if any; and

(iii) the name, address, and Social Security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, unless the stock is traded on a major stock exchange and not traded over the counter;

(D) if a limited liability company, the name of each manager and member, the name and federal employer identification number of the limited liability company, and the name of the state where organized; and

(E) if a sole proprietorship, the full name, address, Social Security number, and date of birth of the sole proprietor and the name and federal employer identification number of the business entity.

(6) The name, address, and telephone number of the designated

representative of each facility.

(7) Additional information concerning record keeping required under this chapter.

(b) The board shall require a wholesale drug distributor to post a surety bond of at least one hundred thousand dollars ($100,000), or an equivalent means of security acceptable to the board, including insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties that may be imposed by the board and any fees and costs that may be incurred by the board and that:

(1) are related to a license held by the wholesale drug distributor;

(2) are authorized under Indiana law; and

(3) the wholesale drug distributor fails to pay less than thirty (30) days after the penalties, fees, or costs become final.

However, a separate surety bond or an equivalent means of security is not required for a separate location or a company of the wholesale drug distributor.

(c) The board may make a claim against a bond or security posted under subsection (b) within one (1) year after the wholesale drug distributor's license is no longer valid or sixty (60) days after the conclusion of:

(1) an administrative or legal proceeding before or on behalf of the board that involves the wholesale drug distributor and results in penalties, fees, or costs described in subsection (b); or

(2) an appeal of a proceeding described in subdivision (1);

whichever occurs later.

(d) The board **or the board's designee** shall inspect each facility where wholesale distribution operations are conducted before initial licensure and periodically thereafter in accordance with a schedule determined by the board, but at least one (1) time in each three (3) year period.

(e) A wholesale drug distributor must publicly display or have readily available all licenses and the most recent inspection report administered by the board **or the board's designee.**

(f) A material change in any information in this section must be submitted to the board at the time of license renewal or within thirty (30) days from the date of the change, whichever occurs first.

SECTION 18. IC 25-26-14-16, AS AMENDED BY P.L.212-2005, SECTION 50, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 16. (a) In reviewing, for purposes of licensure or renewal of a license under this chapter, the qualifications of persons who engage in wholesale distribution of legend drugs in Indiana, the

board shall consider the following factors:

(1) A finding by the board that the applicant has:

(A) violated a law; or

(B) been disciplined by a regulatory agency for violating a law;

related to drug distribution in any state.

(2) A criminal conviction of the applicant.

(3) The applicant's past experience in the manufacture or distribution of legend drugs, including controlled substances.

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution.

(5) Suspension or revocation of any license held by the applicant or the applicant's owner or the imposition of sanctions against the applicant or the applicant's owner by the federal or a state or local government for the manufacture or distribution of any drugs, including controlled substances.

(6) Compliance with licensing requirements under previously granted licenses.

(7) Compliance with requirements to maintain and make available to the board or to federal, state, or local law enforcement officials those records required under this chapter.

(8) Any other factors or qualifications the board considers relevant to the public health and safety, including whether the granting of the license would not be in the public interest.

(b) ~~After December 31, 2005,~~ In reviewing an application for licensure or renewal of a license under this chapter, the board shall consider the results of ~~a national~~ criminal history **and financial** background ~~check (as defined in IC 10-13-3-12)~~ **checks** for:

~~(1)~~ the applicant;

~~(2) all personnel involved in the operations of the wholesale drug distributor;~~

~~(3)~~ **(1) the designated representative or** the most senior individual responsible for facility operations, purchasing, and inventory control; ~~and the individual to whom the senior individual reports;~~

~~(4) company officers;~~

~~(5) key management personnel;~~

~~(6) principals; and~~

~~(7)~~ **(2) the supervisor or the designated representative or the most senior individual under subdivision (1); and**

(3) principals and owners with ~~at least~~ **more than** a ten percent

(10%) interest in the wholesale drug distributor, if the wholesale drug distributor is a nonpublicly held company.

(c) The ~~national~~ criminal history **and financial** background ~~check~~ **checks conducted under subsection (b)** must:

(1) be conducted at the applicant's expense; ~~and must~~

(2) include **a criminal history for** all **current and previous** states of residence ~~since~~ **of** the applicant; ~~became eighteen (18) years of age.~~

(3) include the criminal history in the federal district where the applicant currently resides;

(4) include information from the previous seven (7) years; and

(5) be approved by the board.

~~(c) After December 31, 2005,~~ **(d)** An applicant shall provide and attest to:

(1) an affirmation that the applicant has not been involved in or convicted of any criminal or prohibited acts; or

(2) a statement providing a complete disclosure of the applicant's past criminal convictions and violations of state and federal laws; regarding drugs.

SECTION 19. IC 25-26-14-16.5, AS ADDED BY P.L.212-2005, SECTION 51, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 16.5. (a) A wholesale drug distributor shall designate in writing on a form prescribed by the board a designated representative for each of the wholesale drug distributor's facilities licensed under this chapter.

(b) A designated representative shall submit to the board an application prescribed by the board and provide to the board the following:

~~(1) A set of the designated representative's fingerprints, under procedures specified by the board and according to requirements of the state police department under IC 10-13-3-38.5, with payment of the amount equal to the costs of a national criminal history background check (as defined in IC 10-13-3-12) of the designated representative to be obtained by the state police department.~~

~~(2)~~ **(1)** The date and place of birth of the designated representative.

~~(3)~~ **(2)** A list of the occupations, positions of employment, and offices held by the designated representative during the immediately preceding seven (7) years, including the principal business and address of the organization with which the occupation, position, or office was associated.

~~(4)~~ **(3)** A statement concerning whether the designated

representative, during the immediately preceding seven (7) years, has been temporarily or permanently enjoined by a court from violating a state or federal law regulating the possession, control, or distribution of legend drugs, including details of related events.

~~(5)~~ **(4)** A description of any involvement by the designated representative with a business that:

(A) manufactured, administered, prescribed, distributed, or stored legend drugs; and

(B) was named as a party in a lawsuit;

during the immediately preceding seven (7) years, including investments other than the ownership of stock in a publicly traded company or mutual fund.

~~(6)~~ **(5)** A description of any criminal offense of which the designated representative has been convicted, regardless of whether adjudication of guilt was withheld or whether the designated representative pleaded nolo contendere. If the designated representative indicates that a criminal conviction is under appeal, the designated representative shall submit to the board:

(A) a copy of the notice of appeal; and

(B) a copy of the final written order of disposition.

~~(7)~~ **(6)** A photograph of the designated representative taken within the immediately preceding thirty (30) days under procedures specified by the board.

~~(8)~~ **(7)** A list of the name, address, occupation, and date and place of birth of each member of the designated representative's immediate family, including the designated representative's spouse, children, parents, and siblings, and the spouses of the designated representative's children and siblings. Information collected under this subdivision is confidential.

~~(9)~~ **(8)** Any other information required by the board.

(c) A designated representative must have at least two (2) years of verifiable full-time managerial or supervisory experience in a pharmacy or with a wholesale drug distributor licensed under this chapter or in another state. The designated representative's responsibilities must have included record keeping, storage, and shipment of legend drugs.

(d) A designated representative shall not serve as the designated representative for more than one (1) wholesale drug distributor facility at any one (1) time.

(e) A designated representative shall be actively involved and aware of the actual daily operations of the wholesale drug distributor as follows:

(1) Be employed full time in a managerial position by the wholesale drug distributor.

(2) Be physically present at the wholesale drug distributor's facility during normal business hours, except when absent due to illness, family illness or death, scheduled vacation, or another authorized absence.

(3) Be aware of and knowledgeable about all policies and procedures pertaining to the operations of the wholesale drug distributor.

(f) A designated representative must complete continuing education programs specified by the board regarding state and federal law relevant to the distribution, handling, and storage of legend drugs.

(g) A third party logistics provider must comply with this subsection until the third party logistics provider has obtained accreditation. A third party logistics provider must identify to the board a designated representative who is responsible for the facility's compliance with applicable state and federal law. The designated representative:

(1) may be a corporate employee or officer, outside counsel, or an outside consulting specialist with authority to help ensure compliance;

(2) may be responsible for multiple facilities; and

(3) is not required to be physically present at the facility.

SECTION 20. IC 25-26-14-17, AS AMENDED BY P.L.212-2005, SECTION 53, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 17. As a condition for receiving and retaining a wholesale drug distributor license issued under this chapter, an applicant must satisfy the board that the applicant has and will continuously maintain the following:

(1) Acceptable storage and handling conditions and facilities standards for each facility at which legend drugs are received, stored, warehoused, handled, held, offered, marketed, or displayed, or from which legend drugs are transported, including:

(A) suitable construction of the facility and appropriate monitoring equipment to ensure that legend drugs in the facility are maintained in accordance with labeling or in compliance with official compendium standards;

(B) suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

(C) adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(D) a quarantine area for separate storage of legend drugs that

are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened;

(E) maintenance of the facility in a clean and orderly condition;

(F) maintenance of the facility in a commercial, nonresidential building; and

(G) freedom of the facility from infestation.

(2) Security of each facility from unauthorized entry as follows:

(A) Entry into areas where legend drugs are held is limited to authorized personnel.

(B) Each facility is equipped with a security system that includes:

(i) an after hours central alarm or a comparable entry detection capability;

(ii) restricted premises access;

(iii) adequate outside perimeter lighting;

(iv) safeguards against theft and diversion, including employee theft and theft or diversion facilitated or hidden by tampering with computers or electronic records; and

(v) a means of protecting the integrity and confidentiality of data and documents and of making the data and documents readily available to the board and other state and federal law enforcement officials.

(3) A reasonable system of record keeping as follows:

(A) The system describes all the wholesale distributor's activities governed by this chapter for the three (3) year period after the disposition of each product, and all records are maintained for at least three (3) years after disposition of the legend drug to which the record applies.

(B) The system is reasonably accessible as determined by board rules in any inspection authorized by the board.

(C) The system provides a means to establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of all legend drugs, including the following:

(i) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is an authorized distributor, a pedigree for each distributed legend drug that leaves the normal distribution chain of custody, as determined by rules adopted by the board.

(ii) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is not an authorized distributor, a pedigree for each distributed legend drug **that leaves the normal chain of custody.**

(iii) After January 1, 2007, and after consulting with the federal Food and Drug Administration, at the board's discretion, for each legend drug received and distributed by the wholesale drug distributor, an electronic pedigree developed in accordance with standards and requirements of the board to authenticate, track, and trace legend drugs. The standards and requirements of the board may indicate the information required to be part of the electronic pedigree.

(iv) Dates of receipt and distribution or other disposition of the legend drugs by the wholesale drug distributor.

(v) Availability for inspection and photocopying by any authorized official of a local, state, or federal governmental agency for three (3) years after the creation date of the inventories and records.

(D) Onsite electronic inventories and records are immediately available for inspection, and records kept at a central location apart from the inspection site and not electronically retrievable are available for inspection within two (2) working days after a request by an authorized official of a local, state, or federal governmental agency.

(E) The system maintains an ongoing list of persons with whom the wholesale drug distributor does business.

(F) The system provides for reporting counterfeit or suspected counterfeit legend drugs or counterfeiting or suspected counterfeiting activities to the board and the federal Food and Drug Administration.

(G) The system provides for mandatory reporting of significant shortages or losses of legend drugs to the board and the federal Food and Drug Administration, **if applicable,** if diversion is known or suspected.

(4) Written policies and procedures to which the wholesale drug distributor adheres for the receipt, security, storage, inventory, transport, shipping, and distribution of legend drugs, and that assure reasonable wholesale distributor preparation for, protection against, and handling of any facility security or operation problems, including the following:

(A) Facility security or operation problems caused by natural disaster or government emergency.

(B) Correction of inventory inaccuracies.

(C) Product shipping and receiving problems.

(D) Quarantine and return to the manufacturer or destruction in accordance with state and federal law of all outdated products and outdated or expired legend drugs, including appropriate documentation and witnessing.

(E) Appropriate disposition of returned goods.

(F) Product recalls.

(G) Identifying, recording, and reporting losses or thefts.

~~(H) Implementation and maintenance of a continuous quality improvement system.~~

~~(I)~~ **(H)** Recalls and withdrawals of legend drugs due to:

(i) an action initiated by the federal Food and Drug Administration or another federal, state, or local governmental agency;

(ii) a volunteer action by the manufacturer to remove defective or potentially defective legend drugs from the market; or

(iii) an action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.

~~(J)~~ **(I)** Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.

~~(K)~~ **(J)** Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband legend drugs and reporting of discrepancies within three (3) business days to the board and any other appropriate state or federal governmental agency.

~~(L)~~ **(K)** Reporting of criminal or suspected criminal activities involving the inventory of legend drugs to the board within three (3) business days.

~~(M)~~ **(L)** Conducting for cause authentication ~~and random authentication~~ as required under sections 17.2 ~~17.3,~~ and 17.8 of this chapter.

(5) Written policies and procedures and sufficient inspection procedures for all incoming and outgoing product shipments, including the following:

(A) Upon receipt, visual examination of each shipping container in a manner adequate to identify the legend drugs in

the container and to determine whether the legend drugs may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution.

(B) Upon receipt, review of records by the wholesale drug distributor for the acquisition of legend drugs for accuracy and completeness, considering the:

(i) total facts and circumstances surrounding each transaction involving the legend drugs; and

(ii) wholesale drug distributors involved.

(C) Quarantine of a legend drug considered to be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution until:

(i) examination and a determination that the legend drug is not outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution; or

(ii) the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.

~~(D) Written policies and procedures to ensure that a legend drug that was:~~

~~(i) ordered in error or in excess of need by the wholesale drug distributor;~~

~~(ii) identified within three (3) business days after receipt as ordered in error or in excess of need; and~~

~~(iii) maintained such that the legend drug's integrity has not been compromised;~~

~~may be returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired if the appropriate documentation is completed and necessary notations are made to a required pedigree.~~

~~(E)~~ **(D)** Written policies and procedures to ensure that if the wholesale drug distributor determines that a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.

~~(F)~~ **(E)** Written policies and procedures to ensure that if the immediate or sealed outer or secondary container or labeling of a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor:

(i) quarantines the legend drug until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired; and

(ii) provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.

~~(G)~~ **(F)** Written policies and procedures to ensure that a legend drug that has been opened or used, but is not adulterated, misbranded, counterfeit, or suspected counterfeit, is identified as such and quarantined until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.

~~(H)~~ **(G)** Written policies and procedures to ensure that:

(i) a legend drug that will be returned to a manufacturer or wholesale drug distributor is kept under proper conditions for storage, handling, transport, and shipment before the return; and

(ii) documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale drug distributor to which the legend drug is returned.

~~(I)~~ **(H)** Inspection of each outgoing shipment for identity of the legend drugs and to ensure that the legend drugs have not been damaged in storage or held under improper conditions.

~~(J)~~ **(I)** Written policies and procedures to ensure that if conditions under which a legend drug has been returned to the wholesale drug distributor cast doubt on the legend drug's safety, identity, strength, quality, or purity, the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired unless examination, testing, or other investigation proves that the legend drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a legend drug has been returned cast doubt on the legend drug's safety, identity, strength, quality, or purity, the wholesale drug distributor considers the conditions under which the legend drug has been held, stored, or shipped

before or during the legend drug's return and the condition of the legend drug and the legend drug's container, carton, or labeling upon receipt of the returned legend drug.

~~(K)~~ **(J)** Written policies and procedures to ensure that contraband, counterfeit, or suspected counterfeit legend drugs, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the board and the federal Food and Drug Administration.

~~(L)~~ **(K)** Written policies and procedures to ensure that any shipping, immediate, or sealed outer or secondary container or labeling, and accompanying documentation, suspected of or determined to be counterfeit or fraudulent, are retained until a disposition is authorized by the board and the federal Food and Drug Administration.

(6) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

(7) Written policies and procedures to provide for the secure and confidential storage of information with restricted access and to protect the integrity and confidentiality of the information.

(8) A pedigree as required under this chapter, including an electronic pedigree developed in accordance with standards and requirements of the board under subdivision (3)(C)(iii).

(9) Appropriate inventory management and control systems to:

(A) prevent; and

(B) allow detection and documentation of;

theft, counterfeiting, or diversion of legend drugs.

(10) If the wholesale drug distributor is involved in the distribution of controlled substances, registration with the federal Drug Enforcement Administration and the board and compliance with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances.

(11) Isolation of controlled substances from noncontrolled substances and storage of the controlled substances in a secure area in accordance with federal Drug Enforcement Administration security requirements and standards.

(12) Technology and equipment that allow the wholesale drug distributor to authenticate, track, and trace legend drugs. The technology and equipment meet standards set by the board and are used as required by the board to conduct for cause and random tracking, tracing, and authentication of legend drugs.

(13) Employment, training, and documentation of the training concerning the proper use of the technology and equipment

required under subdivision (12).

(14) Packaging operations in accordance with an official compendium allowing the identification of a compromise in the integrity of the legend drugs due to tampering or adverse storage conditions.

SECTION 21. IC 25-26-14-17.2, AS ADDED BY P.L.212-2005, SECTION 54, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 17.2. (a) A wholesale drug distributor that purchases legend drugs from another wholesale drug distributor and has reason to believe that a legend drug purchased from the other wholesale drug distributor is counterfeit, suspected counterfeit, misbranded, or adulterated shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.

(b) A wholesale drug distributor that has engaged in the distribution of a legend drug for which a purchasing wholesale drug distributor conducts a for cause authentication under subsection (a) shall provide, upon request, detailed information regarding the distribution of the legend drug, including the:

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

(3) sales invoice number of the legend drug; and

(4) contact information, including name, address, telephone number, and electronic mail address of the wholesale drug distributor that sold the legend drug.

(c) If a wholesale drug distributor conducts a for cause authentication under subsection (a) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration, **if applicable,** not more than ten (10) business days after completing the attempted authentication.

(d) If a wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (a), the wholesale drug distributor shall maintain records of the authentication for three (3) years and shall produce the records for the board and the federal Food and Drug Administration upon request.

SECTION 22. IC 25-26-14-17.8, AS ADDED BY P.L.212-2005, SECTION 56, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 17.8. (a) A wholesale drug distributor licensed under this chapter that purchases legend drugs from a wholesale drug distributor that is not licensed under this chapter shall act with due diligence as required under this section and rules adopted

by the board. **However, the due diligence requirements of this section do not apply to purchases from an unlicensed wholesale drug distributor that has obtained accreditation through the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors program.**

(b) Before the initial purchase of legend drugs from the unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall obtain the following information from the unlicensed wholesale drug distributor:

(1) A list of states in which the unlicensed wholesale drug distributor is licensed.

(2) A list of states into which the unlicensed wholesale drug distributor ships legend drugs.

(3) Copies of all state and federal regulatory licenses and registrations held by the unlicensed wholesale drug distributor.

(4) The unlicensed wholesale drug distributor's most recent facility inspection reports.

(5) Information regarding general and product liability insurance maintained by the unlicensed wholesale drug distributor, including copies of relevant policies.

(6) A list of other names under which the unlicensed wholesale drug distributor does business or has been previously known.

(7) A list of corporate officers and managerial employees of the unlicensed wholesale drug distributor.

(8) A list of all owners of the unlicensed wholesale drug distributor that own more than ten percent (10%) of the unlicensed wholesale drug distributor, unless the unlicensed wholesale drug distributor is publicly traded.

(9) A list of all disciplinary actions taken against the unlicensed wholesale drug distributor by state and federal agencies.

(10) A description, including the address, dimensions, and other relevant information, of each facility used by the unlicensed wholesale drug distributor for legend drug storage and distribution.

(11) A description of legend drug import and export activities of the unlicensed wholesale drug distributor.

(12) A description of the unlicensed wholesale drug distributor's procedures to ensure compliance with this chapter.

(13) A statement:

(A) as to whether; and

(B) of the identity of each manufacturer for which;

the unlicensed wholesale drug distributor is an authorized

distributor.

(c) Before the initial purchase of legend drugs from an unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall:

(1) request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department of all individuals associated with the unlicensed wholesale drug distributor as specified for licensure of a wholesale drug distributor under section 16(b) of this chapter; and

(2) verify the unlicensed wholesale drug distributor's status as an authorized distributor, if applicable.

(d) If an unlicensed wholesale drug distributor's facility has not been inspected by the board or the board's agent within three (3) years after a contemplated purchase described in subsection (a), the licensed wholesale drug distributor shall conduct an inspection of the unlicensed wholesale drug distributor's facility:

(1) before the initial purchase of legend drugs from the unlicensed wholesale drug distributor; and

(2) at least once every three (3) years unless the unlicensed wholesale drug distributor's facility has been inspected by the board, or the board's agent, during the same period;

to ensure compliance with applicable laws and regulations relating to the storage and handling of legend drugs. A third party may be engaged to conduct the site inspection on behalf of the licensed wholesale drug distributor.

(e) At least annually, a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall ensure that the unlicensed wholesale drug distributor maintains a record keeping system that meets the requirements of section 17(3) of this chapter.

(f) If a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor has reason to believe that a legend drug purchased from the unlicensed wholesale drug distributor is misbranded, adulterated, counterfeit, or suspected counterfeit, the licensed wholesale drug distributor shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.

(g) An unlicensed wholesale drug distributor that has engaged in the distribution of a legend drug for which a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) shall provide, upon request, detailed information regarding the

distribution of the legend drug, including the:

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

(3) sales invoice number of the legend drug; and

(4) contact information, including name, address, telephone number, and any electronic mail address of the unlicensed wholesale drug distributor that sold the legend drug.

(h) If a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) and is unable to authenticate each distribution of the legend drug, the licensed wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration within ten (10) business days after completing the attempted authentication.

(i) If a licensed wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (f), the licensed wholesale drug distributor shall maintain records of the authentication for three (3) years and shall provide the records to the board upon request.

(j) A licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall, at least annually, conduct random authentications of required pedigrees on at least ten percent (10%) of sales units of distributions of legend drugs that were purchased from unlicensed wholesale drug distributors.

(k) An unlicensed wholesale drug distributor from which a licensed wholesale drug distributor has purchased legend drugs shall cooperate with the random authentications of pedigrees under this section and provide requested information in a timely manner.

(l) If a wholesale drug distributor conducts a random authentication under subsection (j) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

SECTION 23. IC 25-26-14-17.9, AS ADDED BY P.L.212-2005, SECTION 57, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 17.9. A wholesale drug distributor licensed under this chapter may not use a trade name or business name identical to a trade name or business name used by ~~another~~ **an unrelated** wholesale drug distributor licensed under this chapter.

SECTION 24. IC 25-26-14-18 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 18. **(a)** Any applicant denied a license or renewal under this chapter has the right

of review of the board's action under IC 4-21.5.

(b) An applicant that is denied the accreditation under section 14 of this chapter from an accreditation body that has entered into an agreement with the board has the right of review of the accreditation body's decision by the board.

SECTION 25. IC 25-26-14-20, AS AMENDED BY P.L.212-2005, SECTION 58, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 20. ~~(a)~~ A person employed in wholesale distribution must have appropriate education or experience to assume responsibility for positions related to compliance with licensing requirements.

~~(b) After December 31, 2005, before employing a person to be engaged in the operation and handling of legend drugs, a wholesale drug distributor shall request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department for the person.~~

SECTION 26. IC 25-26-14-27, AS AMENDED BY P.L.212-2005, SECTION 61, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 27. A wholesale drug distributor that fails to comply with the conditions and requirements described in

~~(1)~~ section 17, ~~or~~

~~(2) after December 31, 2005, section~~ 17.2, ~~17.3,~~ 17.8, 17.9, or 20 of this chapter commits a Class D felony.

SECTION 27. IC 25-26-16-3 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 3. (a) At the time of admission to a hospital that has adopted a protocol under this chapter, the following apply:

(1) The admitting practitioner shall signify in writing in the form and manner prescribed by the hospital whether the protocol applies in the care and treatment of the patient.

(2) A pharmacist may adjust the drug therapy regimen of the patient pursuant to the:

(A) written authorization of the admitting practitioner under subdivision (1); and

(B) protocols of the hospital.

The pharmacist shall review the appropriate medical records of the patient to determine whether the admitting practitioner has authorized the use of a specific protocol before adjusting the patient's drug therapy regimen. The admitting practitioner may at any time modify or cancel a protocol by entering the modification or cancellation in the patient's medical record.

(b) Notwithstanding subsection (a)(2), if a protocol involves

parenteral nutrition of the patient, the pharmacist shall communicate with the admitting practitioner to receive approval to begin the protocol. The authorization of the admitting practitioner to use the protocol shall be entered immediately in the patient's medical record, **if required by the protocol.**

SECTION 28. IC 25-26-21-8, AS ADDED BY P.L.122-2005, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 8. (a) After June 30, 2006, a provider must be licensed by the board before the provider may provide home medical equipment services. If a provider provides home medical equipment services from more than one (1) location in Indiana, the provider must obtain a license under this chapter for each location.

(b) An applicant shall submit the application to the board on a form adopted by the board. The nonrefundable application fee set by the board must be submitted with the application. The fee must be deposited in the state general fund.

(c) If the board determines that the applicant:

(1) meets the standards set forth by the board; and

(2) has satisfied the requirements under this chapter and the requirements established by the board by rule;

the board shall notify the applicant in writing that the license is being issued to the applicant. The license is effective on the applicant's receipt of the written notification.

(d) A license issued under this chapter is effective for not more than two (2) years, beginning on a date determined by the board. An entity that is licensed under this chapter shall display the license or a copy of the license on the licensed premises.

(e) The board may renew a license every two (2) years.

(f) The board may adopt rules that permit an out-of-state provider to obtain a license on the basis of reciprocity if:

(1) the out-of-state provider possesses a valid license granted by another state;

(2) the legal standards for licensure in the other state are comparable to the standards under this chapter; and

(3) the other state extends reciprocity to providers licensed in Indiana.

However, if the requirements for licensure under this chapter are more restrictive than the standards of the other state, the out-of-state provider must comply with the additional requirements of this chapter to obtain a reciprocal license under this chapter.

SECTION 29. THE FOLLOWING ARE REPEALED [EFFECTIVE

UPON PASSAGE]: IC 25-26-13-12.5; IC 25-26-14-15.5; IC 25-26-14-17.3.

SECTION 30. **An emergency is declared for this act.**

President of the Senate

President Pro Tempore

Speaker of the House of Representatives

Governor of the State of Indiana

Date: _____ Time: _____